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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/689,637 11/13/00 SCHALM

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HM12/0925  
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EXAMINER

SCHETNER, I

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

09/25/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/689,633

Applicant(s)

Examiner

Group Art Unit

1648

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 7/12/01.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 11-20 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 17 is/are allowed. DRAWN TO ALLOWANCE
- ☒ Claim(s) 11-16 & 18-20 is/are rejected. SUBJECT MATTER
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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Claims 11-20 are pending in this application. This action is supplemental to the action mailed July 3, 2001.

It is suggested that applicants consider amending the claims to conform with Jepson language since based on the prior art and the instant specification's teachings the claims are drawn to improved methods.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicoll et al. (JOURNAL OF GASTROENTEROLOGY AND HEPATOLOGY, 1997, 12(12) 843-54).

Nicoll et al. teach that adefovir is an inhibitor of HBV-DNA replication via a DNA chain terminator mechanism as well as a competitive inhibitor of the viral polymerase. Moreover, Nicoll et al. teach that "9-2-Phosphonylmethoxyethyl adenine has also been shown to increase the activity of natural killer cells and stimulate immune responsiveness, most likely through endogenous IFN- $\alpha$  production." The reference also discusses combination antiviral therapy for chronic hepatitis B wherein various nucleoside analogues are administered in tandem with an additional chemotherapeutic agent such as another nucleoside analogue or IFN- $\alpha$ .

Nicoll et al. fail to teach the instant protocol's 26 weeks or more administration schedule. Also, the reference fails to specifically teach IFN- $\alpha$ /adefovir combination therapy for the treatment of HBV infection.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered IFN- $\alpha$  in combination with the adefovir of Nicoll et al. for the treatment of HBV

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infection since Nicoll et al. clearly teach an increase in immune responsiveness subsequent to adefovir administration due to endogenous interferon. That is, with respect to adefovir, it would not appear that in tandem adefovir/interferon administration would be contraindicated since IFN levels are boosted by the nucleoside analogue and immune-enhancing effects appear to be interferon driven; which is in contrast to lamivudine/IFN- $\alpha$  combination treatment results wherein no improvement with respect to immune-enhancing effects over IFN- $\alpha$  alone was shown.

It is further noted that although Nicoll et al. fail to enable (or teach) the instant more than 26 week treatment protocol, the specification similarly fails to enable the IFN- $\alpha$ /adefovir combination therapy as claimed. That is, applicants teach results for a single patient receiving lamivudine/IFN- $\alpha$  combination treatment only.

Claim 17 is drawn to allowable subject matter and would be allowed if written in appropriate independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

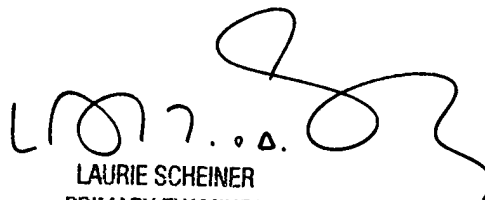
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Laurie Scheiner/LAS  
September 22, 2001



LAURIE SCHEINER  
PRIMARY EXAMINER